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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,746	10/08/2003	Thomas J.F. Nieland	MIT 9952	8136

23579 7590 08/26/2005

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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 08/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/681,746	NIELAND ET AL.	
	Examiner	Art Unit	
	Venkataraman Balasubramanian	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-17 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-17 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 8/27/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-17 are pending.

Information Disclosure Statement

References cited in the Information Disclosure Statement filed on 8/27/2005, are made of record.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Following reasons apply. Any claim not specifically rejected is rejected as being dependent on a rejected claim and share the same limitation

1. Recitation of "compound", "in combination with pharmaceutically acceptable carrier" and "in an effective amount in need of" etc. in claim 1 renders claim 1 and its dependent claims indefinite as it is not clear whether the claim is compound claim or composition claim or a method of use claim.
2. Claim 2 is indefinite for more than one reason. First of all, almost all structures shown in Table 1 on which claim 2 is relying have nitrogen and or oxygen with open valence, salt shown lacks a negative charge and some structures are clearly not discernable as to what they are which would result in printer query. See entire Table. For mention a few, see MIT9952-25, 30, 37, 39, 40, 41, 44, 63,

64, 66, 68, 75, 137, 146, 152, 158, 159, 178, 197, 251, 275, 299, 300, 301, 36, 307, 308, 316, 317, 321 and 342. In short, the entire Table need to be revised for clear depiction of the structures. In addition, the Table also has several structures which are duplicates. See 3, 7, 81 or 16, 83, or 2,80, or 14, 86.

3. Claim 3 is indefinite as it refers to series of compounds without pointing to where these compounds are depicted. Note claim 3 does not refer to Table I and claim 1 on which claim 3 is dependent does not recite these compounds or the Table.

4. Claim 10 is indefinite as it recites a method of identifying a compound which alters SR-B1 binding activity but merely recites screening a library of compounds without reciting how. It is not clear what this method entails. In addition, the dependent claims 11-17 recite limitations which appear to be not part of the method of screening. For example in claim 14, the inhibited SR-B1 activity, as per the limitation 'blocks SR-BI-mediated lipid transport. Thus without knowing what is entailed in the screening process it is not possible to discern how assess this limitation.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for MIT9952-94 and MIT 9952-14, does not reasonably provide enablement for compounds listed in Table 1.. The specification does not enable any person skilled in the art to which it pertains, or with which it is most

nearly connected, to make and use the invention commensurate in scope with these claims. Table 1 lists 342 compounds, of which two of them based on a quick search are commercially available. Specification does not provide one or process for making these compounds or the source for obtaining these compounds It is not clear whether these compounds are known compounds or part of instant invention. If these are part of instant invention, these compounds need to be enabled as species recited are of various structural cores. If these are known compounds tested for the activity, as they appear to, references to these compounds should be made of record. Note the dependent method claims 4-17 are rejected herein as they share the same lack of scope of enablement of the compounds.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 2 is rejected 35 U.S.C 102(b) as being anticipated by Fluorochem and or SynChem OHG

Fluorochem supplies benzoyl-beta-alanine, which is also claimed in the instant claim. See Catalogue : TCI, Cat..No. 80099.

Synchem supplies 6-methoxybenzothiazole-2-carboxylic acid, which is also claimed in the instant claim. See Product a176 with CAS Registry Number : 946-13-4.

It is clear that these compounds are known compounds.

Although claim 2 depends on claim 1 and would share the functional limitation recited in claim1, a compound is a compound irrespective of is functional property.

See Intirtool, LTD. V. Texar Corp., 70 USPQ2D 1780. Note court held that " In general, a claim preamble is limiting if recites essential structure or steps or if it is necessary to give" life, meaning, and vitality to claim.'.... However, if the body of the claim describes a structurally complete invention such that deletion of the preamble phrase does not effect the structure or steps of the claimed invention,' the preamble is generally not limiting unless there is clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art.""

Instant claim is a composition claim of compound and the compound is clearly defined by a structure shown in Table 1. Omission of the attributes to the composition of the compounds of Table 1 would not alter the structure of these compounds and hence the composition.

See also In re Best 195 USPQ 430. Particularly note In re Best has the following quote " Where Patent Office has reason to believe that functional limitation asserted to be critical for establishing novelty in the claimed subject matter, may, in fact, be an inherent characteristic in the prior art, it possesses the authority to require applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on". See MPEP 2112.

Since the instant claim is not a method of use claim, this rejection is proper.

Claims 1 and 4-17 are rejected 35 U.S.C 102(b) as being anticipated by Krieger et al., US2002/0099040.

Krieger et al., teaches several SR-B1 antagonists and their use, which include generically claimed instant compound and the method of use.

See entire document. Especially see pages 2-10, paragraphs 0012 to 0112 for details of the SR-B1, HDL , cholesterol transport, compounds that interact with SR-B1 or alter is expression, inhibition of uptake, binding or transport to SR-B1, screening assay, Northern analysis as well as pages 10-16 for examples 1-6 . Note teachings of Krieger in these pages meet all the limitations claimed in claims 1 and 4-17.

Claims 1 and 4-17 are rejected 35 U.S.C 102(b) as being anticipated by Luchoomun et al. US 2002/0016364.

Luchoomun et al. et al. teaches several compounds that interact with SR-B1, increase plasma HDL.cholesterol levels and improve HDL functionality. See entire document including Figure 1-5 for results of the interaction f compound A-D with SR-B1 and their effect on HDL. Especially see pages 1-10 for details of SR-B1 and its role along with HDL in cholesterol transport, various compounds that alter cholesterol levels in blood. See also pages 16-25 for the invention of Luchoomun et al., namely probuchol analogs and their use. Se pages 26-31 for various assays and examples 1-7. Note all the compounds taught by Luchoomun et al. is also generically claimed in the instant claims 1 and that all the limitations recited in claims 4-17 are also taught by Luchoomun et al.

Claims 1 and 4-17 are rejected 35 U.S.C 102(b) as being anticipated by Acton US 5.965,790

Acton teaches several compounds that alter SR-B1 expression, its role in lipid transfer, cholesterol transport along with screening assays for discovering drugs that regulate the expression of Sr-B1. See entire document. Especially see column 1-14 for details of SR-B1 and its role n lipid and cholesterol transport. Particularly see column 9-10 for small molecules that interact with the gene and regulate Sr-B1 expression as well as column 12-31 for various assays for screening and evaluating such compounds. See claims 18-24 for the same. Note all the compounds taught by Acton are also generically claimed in the instant claims 1 and all the limitations recited in claims 4-17 are also taught by Acton.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1and 4-17 are rejected under 35 U.S.C. 103(a) as being unpatentable by Krieger et al., US2002/0099040..

Teachings of Krieger et al., as discussed in the above 102 rejection is incorporated herein. As noted above, Krieger et al., teaches several SR-B1 antagonists and their use, which include generically claimed instant compound and the method of use. Krieger et al. does not teach all compounds that interact with SR-B1 but exemplifies only few of them in the examples 1-6. However, Krieger et al. teaches equivalency of those compounds taught with those generically recited. See page 1, paragraph 0007 to 0010, as well as claims 1-17.

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to screen for compounds using the teachings of Krieger et al and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

Claims 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Luchoomun et al. US 2002/0016364.

Teachings of Luchoomun et al., as discussed in the above 102 rejection is incorporated herein. As noted above, Luchoomun et al. et al. teaches several compounds that interact with SR-B1, increase plasma HDL.cholesterol levels and improve HDL functionality. See entire document including Figure 1-5.

However, Luchoomun et al. does not teach all compounds generically recited as those interact with SR-B1 but exemplifies only few of them in the examples 1-6. However, Luchoomun et al. teaches equivalency of those compounds taught with those generically recited. In addition, Luchoomun et al., in pages 3-6 under existing therapies, teaches large set of compounds which also interact with HDL

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to screen for compounds using the teachings of Luchoomun et al and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

Claims 1 and 4-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acton US 5.965,790

Teachings of Acton as discussed in the above 102 rejection is incorporated herein. Acton teaches several compounds that alter SR-B1 expression, its role in lipid transfer, cholesterol transport along with screening assays for discovering drugs that regulate the expression of Sr-B1.

However, Acton does not teach all compounds generically recited as those interact with SR-B1 expression but exemplifies only few of them in the examples 1-6. However, Krieger et al. teaches equivalency of those compounds taught with those generically recited. See column 2, lines 50-62.

Thus it would have been obvious to one having ordinary skill in the art at the time of the invention was made to screen for compounds using the teachings of Acton and expect resulting compounds to possess the uses taught by the art in view of the equivalency teaching outline above.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Acting Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

Venkataraman Balasubramanian

8/19/2005